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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,140

Applicant(s)

HAWTIN, BRIAN

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,9-13,15,17,21-23,28,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,9-13,15,17,21-23,28,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claims 1, 3-5, 9-13, 15, 17, 21-23, 28, 30-31 are pending. The Amendment filed 9/25/02, Paper No. 12, cancelled claims 20 and 29, amended claims 1, 4, 13, 15, 17, 21, and 22, and added claim 31. It is noted that the Amendment requested that "new Claim 30" be added. However, a claim 30 already existed. Thus, under Rule 126, "new Claim 30" is actually new claim 31.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-5, 9-13, 15, 17, 21-23, 29 and 30-31 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the Declaration filed 9/25/02, Paper No. 13, it is noted that the Examiner's response to the Declaration can be found in the Advisory Action mailed 10/9/02, Paper No. 14.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/9/02 has been entered.

Claim Objections

Claim 30 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 30 not been further treated on the merits.

Claim Rejections - 35 USC § 112

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. PPG-5 Ceteth-20 is neither recited in the original specification or claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, 9-13, 15, 17, 21-23, 29, 31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "said composition further comprising an aqueous phase and an oil phase" in claim 1 (lines 4-5) is vague and indefinite, as it is confusing. Is there an aqueous phase and an oil phase apart from the surfactant, alcohol, and drug, or do the surfactant, alcohol, and drug make up parts of the aqueous phase and oil phase of the composition?

(ii) The term "balanced" in claim 3 is a relative term which renders the claim indefinite. The term "balanced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What differentiates an unbalanced amphoteric surfactant from a balanced one?

(iii) Claim 10 is vague and indefinite, as it does not further limit claim 1, from which it depends, as claim 1 recites an aqueous phase and an oil phase in its composition.

(iv) Claim 13 is vague and indefinite, as it is confusing. How can claim 13 recite a composition that consists essentially of certain ingredients, but depend from claims that recite compositions that comprise recited ingredients and an array of unknown ingredients? Re-writing this as an independent claim will overcome this rejection.

(v) Claims 17 and 21 are rejected for the use of improper Markush groups. See MPEP 2173.05(h) for examples of proper conventional or alternative Markush-type language (e.g., “. . .selected from the group consisting of . . .and . . .”). Substituting the term “and” for the term “or” in the last lines on these claims will overcome this rejection.

(vi) Claim 23 is vague and indefinite, as it is confusing. What does it mean that the composition is adapted?

(v) Claims 23 and 28 are vague and indefinite, as they depend on claims that have been cancelled. This rejection can be overcome by inserting the number of the claims that are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 5, 10, 11, 12, 17, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085) and Sang et al. (6,143,310).

The instant invention is directed toward a composition comprising an amphoteric surfactant, a polypropoxylated cetyl alcohol, a polar selected from sodium cromoglycate and nedocromil sodium, and an aqueous and oil phase.

Totten et al. teach compositions of nedocromil for dermatological use. Oil-in-water emulsions are preferred forms of the compositions. The oil phase can comprise surfactants, such as cetomacrogol ethers, wherein cetomacrogol ether is an ethoxylated cetyl alcohol. Topical administration of the composition is disclosed. The composition is filled into 20ml tubes. The reference lacks polypropoxylated cetyl alcohol and an amphoteric surfactant. See pg. 2, line 18- pg. 3, line 7; pg. 4, line 1-pg. 5, line 5; pg. 6, lines 19-22; pg. 7, lines 5-23; pg. 9-pg. 12.

Jacobs et al. teach skin smoothing compositions. Oil-in-water emulsions are taught, wherein disodium cocoamphodiacetate is a preferred surfactant. Disodium cocoamphodiacetate functions as an oil-in-water emulsion stabilizer and as a skin smoothing agent. See Col. 4.

Sang et al. teach cosmetic compositions. PPG-5-Ceteth is taught as a preferred alkoxyated cetyl alcohol that acts as a surfactant and solublizes negatively charged active agents. See Col. 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the disodium cocoamphodiacetate of Jacobs et al. to the composition of Totten et al. because of the expectation of stabilizing the oil-in-water emulsion and smoothing the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the PPG-5-ceteth of Sang in substitution for the cetomacrogol ether of Totten et al. because a) Sang et al. and Totten et al. are both directed toward skin cosmetic compositions; b) Totten et al. teach that additional surfactants can be added to his composition, especially

alkoxylated surfactants; c) Sang et al. teach PPG-5-ceteth as both polyethoxylated and polypropoxylated, wherein these compounds are useful as surfactants for stabilizing emulsions and negatively charged active agents; thus, one of skill in the art would be motivated to substitute one for the other because of the expectation of achieving similar surfactant properties and as providing stability to the negatively charged active agent.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobson et al. and Sang et al. as applied to claims 1, 3, 4, 5, 10, 11, 12, 17, 23, 28, and 30 above, and further in view of Dener et al. (WO 98/04537) and Haider (1979).

Totten et al., Jacobson et al., and Sang et al. are applied as discussed above. The references lack corticosteroids.

Dener et al. teach compositions for treating hyperproliferative skin diseases and inflammatory skin conditions. Cromolyn and nedocromil are taught as equivalent cromoglycates. See abstract.

Haider teaches the treatment of atopic eczema with sodium cromoglycate. Compositions comprising sodium cromoglycate and hydrocortisone are disclosed to treat patients with severe inflammation. See pages 572-573.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the hydrocortisone of Haider to the composition of the combined references because a) Dener et al. teach cromolyn and nedocromil as equivalent cromoglycates for use in skin conditions, and Totten et al. teach nedocromil for the treatment of skin conditions; b) Haider teaches the combination of sodium cromoglycate (cromolyn) and hydrocortisone as treating significant inflammation in patient's with eczema (an inflammatory skin condition); thus, one of

skill in the art would be motivated to add hydrocortisone to the composition of the combined references because of the expectation of synergistically decreasing the inflammation of skin conditions.

Claims 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobs et al.

Totten et al. teach compositions of nedocromil for dermatological use. Oil-in-water emulsions are preferred forms of the compositions. The oil phase can comprise surfactants, such as cetomacrogol ethers, wherein cetomacrogol ether is an ethoxylated cetyl alcohol. Topical administration of the composition is disclosed. The reference lacks an amphoteric surfactant. See pg. 2, line 18-pg. 3, line 7; pg. 4, line 1-pg. 5, line 5; pg. 6, lines 19-22; pg. 7, lines 5-23; pg. 9-pg. 12.

Jacobs et al. teach skin smoothing compositions. Oil-in-water emulsions are taught, wherein disodium cocoamphodiacetate is a preferred surfactant. Disodium cocoamphodiacetate functions as an oil-in-water emulsion stabilizer and as a skin smoothing agent. See Col. 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the disodium cocoamphodiacetate of Jacobs et al. to the composition of Totten et al. because of the expectation of stabilizing the oil-in-water emulsion and smoothing the skin.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobs et al. as applied to claims 15 and 21 above, and further in view of Sang et al.

Totten et al. and Jacobs et al. are applied as discussed above. The reference lacks polypropoxylated cetyl alcohol.

Sang et al. teach cosmetic compositions. PPG-5-Ceteth is taught as a preferred alkoxylated cetyl alcohol that acts as a surfactant and solublizes negatively charged active agents. See Col. 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the PPG-5-ceteth of Sang in substitution for the cetomacrogol ether of the combined references because a) Sang et al. and the combined references are both directed toward skin cosmetic compositions; b) the combined references teach that additional surfactants can be added to his composition, especially alkoxylated surfactants; c) Sang et al. teach PPG-5-ceteth as both polyethoxylated and polypropoxylated, wherein these compounds are useful as surfactants for stabilizing emulsions and negatively charged active agents; thus, one of skill in the art would be motivated to substitute one for the other because of the expectation of achieving similar surfactant properties and as providing stability to the negatively charged active agent.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobson et al. as applied to claims 15 and 21 above, and further in view of Dener et al. and Haider.

Totten et al. and Jacobson et al. are applied as discussed above. The reference lacks corticosteroids.

Dener et al. teach compositions for treating hyperproliferative skin diseases and inflammatory skin conditions. Cromolyn and nedocromil are taught as equivalent cromoglycates. See abstract.

Haider teaches the treatment of atopic eczema with sodium cromoglycate. Compositions comprising sodium cromoglycate and hydrocortisone are disclosed to treat patients with severe inflammation. See pages 572-573.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the hydrocortisone of Haider to the composition of the combined references because a) Dener et al. teach cromolyn and nedocromil as equivalent cromoglycates for use in skin conditions, and Totten et al. teach nedocomil for the treatment of skin conditions; b) Haider teaches the combination of sodium cromoglycate (cromolyn) and hydrocortisone as treating significant inflammation in patient's with eczema (an inflammatory skin condition); thus, one of skill in the art would be motivated to add hydrocortisone to the composition of the combined references because of the expectation of synergistically decreasing the inflammation of skin conditions.

Allowable Subject Matter

Upon overcoming the 112 rejection above, claim 13 will be allowable. The composition recited in instant independent claim 13 is neither anticipated nor rendered obvious over the prior art. The closest prior art is GB 2202145, which teaches a composition comprising 4% glyceryl monostearate, 10% liquid paraffin, 5% isopropyl myristate, 67.22% water, and 4% of a polar drug, and other ingredients. However this composition lacks disodium edetate, amphoteric surfactant, alkoxylated cetyl alcohol, triclosan, sorbitan tristearate or non-ionic emulsifying wax, and benzyl alcohol, and this composition additionally contains Cremophor A6, Cremophor A25, propyl hydroxybenzoate, methyl hydroxybenzoate, potassium sorbate, sodium acid citrate, and sodium hydroxide.

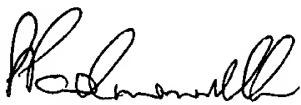
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
January 13, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER 1/20/03